

K030576



MAY 21 2003

Exhibit 07:

510(k) SUMMARY: – Anspach Irrigation System

The Anspach Irrigation Pump System is designed to deliver a constant flow (0 to 30 mL/min) of irrigation fluid by means of a peristaltic pump. The peristaltic pump itself is integral to the control box which is designed for placement on a table or equipped with a connection device to permit secure attachment to an IV Pole. Anspach Irrigation pump systems are designed to be compliant with requirements of UL 2601-1/C, SA 601.1, IEC 60601-1 for UL Classification and EMC Testing.

Operation Characteristics:

*For surgical use, the pump system is set upon a table in the OR (or attached and clamped to an IV pole) A bag(s) of irrigation fluid is hung and the pre-sterilized Irrigation tubing set is connected to the bag. The peristaltic section of the irrigation tubing set is inserted into the peristaltic pump and the pump lid closed and secured. An irrigation clip assembly is inserted into the end of the irrigation tube and with the self-contained motor clips, attached to the surgical drill motor. During surgery the flow of the irrigation fluid is adjusted by the hand control or, for some pneumatic system, adjusted by foot pedal control.

INDICATIONS / CONTRAINDICATIONS:

Anspach Surgical Irrigation Systems are indicated for use with Anspach Surgical Motor Systems for providing controlled, cooling irrigation during cutting, shaping and removal of bone, including bones of the skull and spine.

Anspach Surgical Irrigation Systems are contraindicated for use with any fluids other those specifically for surgical irrigation.

CLEANING/STERILIZATION/MAINTENANCE:

Anspach Irrigation Pumps are not designed to be immersed into any liquids during cleaning. Manual cleaning with mild soap and water is recommended. There is no sterilization required for the pump but disinfectants used for other non-immersable, non-sterilized hospital equipment may be used to disinfect outer surfaces.

WARNINGS:

For safe and effective use of any Anspach product, it is strongly suggested that specialized training be undertaken since surgical techniques using Anspach products are highly specialized and complex procedures. Improper surgical technique or improper use of Anspach products can cause severe injury or death to a user or patient and cause severe damage to Anspach products and/or other manufacturer's or user facility's equipment.

Anspach Companies

4500 Riverside Drive, Palm Beach Gardens, Florida 33410

Phone (561) 627-1080 • Fax (561) 627-3120

Toll Free Phone (800) 327-6887 • Toll Free Fax (800) 327-6661

CAUTIONS:

Generic cautions for use of Anspach Motor Systems, Attachments and Cutters are specified on product inserts and surgical manuals.

SUBSTANTIAL EQUIVALENCE:

The peristaltic pump unit is identical (thus substantially equivalent) to the peristaltic pump used on the Anspach eMax Motor system (K011444). The Irrigation system is substantially equivalent to the "Hall Ultrapower Irrigation Unit (Zimmer K852143), in that it is a peristaltic pump and control box, that is used with an irrigation tubing set and clip assembly. Materials, design and indications for use are nearly identical.

| Principle Differences Between Predicate Devices/Methods and Anspach System | | Hall | Anspach eMax | Anspach PUMP I | Anspach Pump II |
|----------------------------------------------------------------------------|---------------------------------------------|-----------|--------------|----------------|-----------------|
| 01 | US Classification | II | II | II | II |
| 02 | EU Classification | Ila | Ila | Ila | Ila |
| 03 | Manually Powered | No | No | No | No |
| 04 | Externally powered | | | | |
| | Gas/air | No | No | No | No |
| | Electric | Yes | Yes | Yes | Yes |
| 05 | Table-top | Yes | Yes | Yes | Yes |
| 06 | IV Pole mounted | Yes* | No | No | Yes |
| 07 | Indicated for Skull/Spine Procedures | ? | Yes | Yes | Yes |
| 08 | UL Safety tested | ? | Yes | Yes | Yes |
| 09 | Similarity in Materials | Yes | Yes | Yes | Yes |
| 10 | Reusable Device (pump) | Yes | Yes | Yes | Yes |
| 11 | Single Use Irrigation Tubing system | Yes | Yes | Yes | Yes |
| 12 | Single use Irrigation clip assembly | Yes | Yes | Yes | Yes |
| 13 | Cleaning Immersable | No | No | No | No |
| 14 | Recommended Sterilization Method | Disinfect | Disinfect | Disinfect | Disinfect |

* Must be manually modified to permit IV Pole mounting



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Mr. William G. Conety
Director, Regulatory Affairs
and Quality Assurance
The Anspach Effort, Inc.
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K030576
Trade/Device Name: Surgical Irrigation System
Regulation Number: 21 CFR 880.5728
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: FRN
Dated: February 21, 2003
Received: February 24, 2003

Dear Mr. Conety:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

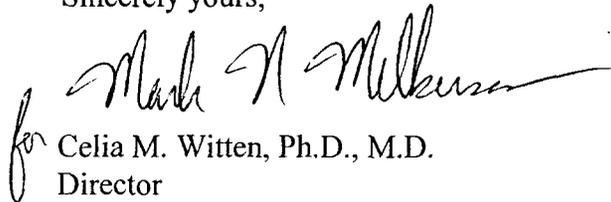
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. William G. Conety

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark A. Milburn". The signature is written in a cursive style with a long horizontal stroke at the end.

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K030576

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Device Name: "Surgical Irrigation System"

INDICATIONS FOR USE:

Anspach Surgical Irrigation Systems are indicated for use with Anspach Surgical Motor Systems for providing controlled, cooling irrigation during cutting, shaping and removal of bone, including bones of the skull and spine.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K030576

Prescription Use: OR Over-the-Counter Use: Per 21 CFR 801.109)